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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,387	03/26/2003	Maurizio Dalle Carbonare	0259-0411PUS1	6340

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
05/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/019,387	DALLE CARBONARE ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-8 and 12-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-8 and 12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks, Amendments and Declarations all filed on 03/11/09 is acknowledged.

Claims 1-2 and 9-11 have been canceled in this Application.

Claims 3, 12-14 and 18 have been amended.

Accordingly, claims 3-8 and 12-22 are pending in this application, claims **3-8 and 12-22** will be prosecuted on the merits.

The rejections made in the previous office action have been withdrawn in view of applicant's amendments to claims.

Applicant's amendments to the claims necessitated the following new rejections.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 3-8 and 12-22 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Davidson et al. (Clinical materials (1991, presented in IDS) in view of Della Valle et al. (USP 5,658,331).

Davidson et al. teaches hyaluronate derivatives and their application to wound healing and wound repair with reduced **scarring** (see title and page 171, second column). The reference teaches that hyaluronic acid and its derivatives show as biomaterial in wound healing applications. The hyaluronate treated wounds tended to accumulate collagen more slowly hence showing the capacity of such biomaterials in modifying the scarring process. Such ability shows effect in improving wound healing and repair process (see the first page). The reference teaches formulations can be fabricated into gels, films and woven material (see page 172, 1-5 lines. Experimental procedures have been shown on page 172, on both columns. The results show that ability of hyaluronate and its esterified derivatives stimulate early organization of wound site while moderating the excessive accumulation of collagen at the stage of scar formation. (See page 174 column2, lat paragraph).

Davidson et al. do not specifically teach benzyl esters as claimed.

Della Valle et al disclose a bio-compatible artificial skin and a method for the production of said artificial skin employing a benzyl-esterified HA membrane. The method involves the deposition of fibroblasts on the HA membrane followed by the addition of keratinocytes and subsequent co-culturing of the keratinocytes and fibroblasts. (See columns 4 and 5, Example 3). The artificial skin is disclosed for use in treating lesions of the body surface (See claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use benzyl hyaluronic acid esters for the treatment of scarring on the skin by using the composition provided by Della Valle et al motivated by the teachings of Davidson et al. which teaches utilization of hyaluronate esters in wound healing and scarring treatment. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

4. Claims 3-8 and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al. (Clinical materials (1991, presented in IDS) in view of Della Valle et al. (EP 341745).

Davidson et al. teaches hyaluronate derivatives and their application to wound healing and wound repair with reduced scarring (see title and page 171, second column). The reference teaches that hyaluronic acid and its derivatives show as biomaterial in wound healing applications. The hyaluronate treated wounds tended to accumulate collagen more slowly hence showing the capacity of such biomaterials in modifying the scarring process. Such ability shows effect in improving wound healing and repair process (see the first page). The reference teaches formulations can be fabricated into gels, films and woven material (see page 172, 1-5 lines. Experimental procedures have been shown on page 172, on both columns. The results show that ability of hyaluronate and its esterified derivatives stimulate early organization of wound

site while moderating the excessive accumulation of collagen at the stage of scar formation. (See page 174 column2, lat paragraph).

Davidson et al. do not specifically teach auto-cross linked HA as claimed.

Della Valle teaches autocrosslinked HA, with a 5% crosslinked product exemplified. See abstract and examples 2 and 3. The reference further teaches the use of this product in a variety of forms, such as films, sheets and threads. See page 11, lines 10-20. The reference further states that the articles prepared using the HA products are "similar to those already known and commercially available or described in the literature," thereby specifically suggesting the use of this product in place of other similar products known in the art.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to use cross linked hyaluronic acid esters for the treatment of scarring on the skin by using the composition provided by Della Valle et al. Since Davidson et al. teaches utilization of hyaluronate esters in wound healing and scarring treatment and Della velle et al. teaches that hyaluronic esters can be used in pharmaceutical fields. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as cross linked esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

Response to Arguments

5. Applicant's arguments with respect to claims 3-8 and 12-22 have been considered but are moot in view of the new ground(s) of rejection.

6. DECLARATION SUBMITTED UNDER 37 CFR. § 1.132

Applicant argues that the attached are the results of the study conducted and from these results it can be seen that samples D and E according to the present invention exhibited an improvement of about 40% in the wound coverage versus all control samples.

The declaration is insufficient to overcome the rejections made in office action dated 09/04/09 and in view of new rejections.

The prior art discloses the scarring and wound healing effect by benzyl ester and crosslinked esters of hyaluronic acid. The increase in 40% of wound healing is a matter of degree and not an unexpected result where the prior art as discussed above specifically teaches application of hyaluronic acid benzyl derivatives in treating scars and wounds. Additionally applicants have compared alginate esters and hyaluronic esters and have not compared the closest prior art versus the claimed invention.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612